



007024-000536.269687

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:)
Jean A. Chmielewski, et al.) Before the Examiner
Serial No. 10/018,043)
Filed: May 21, 2002) Group Art Unit
PHARMACEUTICAL MATERIALS AND)
METHODS FOR THEIR PREPARATION)
AND USE)

INFORMATION DISCLOSURE STATEMENT

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Information Disclosure Statement
Inventor: Jean A. Chmielewski, et al.
Application No. 10/018,043
Our Ref: 7024-536
Page 1 of 2

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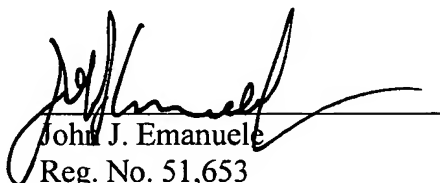
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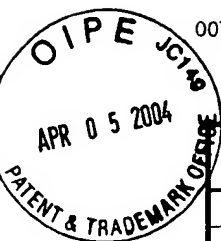
Respectfully submitted:



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		Country Code ² -Number ³ -Kind Code ⁵ (if known)				
		WO 95/24183	9/14/95	Patton et al.		
		WO 98/42367	10/1/98	Jensen et al.		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS						
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		BEAVIS, Ronald C. et al. Epitaxial Protein Inclusion in Sinapic Acid Crystals, J. Phys. D: Appl. Phys. 26 (1993) 442-447.				
		BORMAN, Stu. Biochemical Applications of Mass Spectrometry Take Flight, C&EN, June 19, 1995, 23-32.				
		CARPENTER, J.F. and CROWE, J.H. Infrared Spectroscopic Studies of the Interaction of Carbohydrates with Dried Proteins, Biochemistry, 1989, pp. 3916-22, Vol. 28.				
		CARPENTER, J.F. et al. Separation of Freezing- and Drying-induced Denaturation of Lyophilized Proteins by stress-specific stabilization: I. Enzyme Activity and Calorimetric Studies. Arch. Biochem. Biophys., 1993, pp. 456-64, Vol. 303.				
		CHMIELEWSKI, Jean, et al. Single-Crystal Matrix Isolation of Biopolymers, J. Am. Chem. Soc., 10/29/97, pp. 10565-66, Vol. 119, No. 43.				
		GOKE, R., et al. Exendin-4 is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting Beta-cells. J. Biol. Chem., 9/15/93, pp. 19650-55, 268 (26).				
		HILLENKAMP, Franz, et al. Matrix-Assisted Laser Desorption/Ionization Mass Spectrometry of Biopolymers, Analytical Chemistry, 12/15/91, pp. 1193A-1283A, Vol. 63, No. 24.				
		IZUTSU, K., et al. The Effects of additives on the stability of freeze-dried β -galactosidase stored at elevated temperatures. Int. J. Pharm., 1991, pp. 137-46, Vol. 71.				
		IZUTSU, K., et al. Decreased protein-stabilizing effects of cryoprotectants due to crystallization. Pharm. Res., 1993, pp. 1232-37, Vol. 10.				
		KURIMOTO, Miki et al. Kinetic Stabilization of Biopolymers in Single-Crystal Hosts: Green Fluorescent Protein in α -Lactose Monohydrate, J. Am. Chem. Soc. 1999, Vol. 121, pp. 6952-6953.				
		MALKIN, A.J. et al. Mechanisms of Growth for Protein and Virus Crystals, Nature Structural Biology, Vol. 2, No. 11, November, 1995.				
		POWERS, H.E.C. Sucrose Crystals: Inclusions and Structure, Sugar Technol Rev., I (1969/70) 85-190				
		RASIMAS, J.P. et al. Measuring Self-Assembly in Solution: Incorporation and Dynamics of A "Tailor-Made Impurity" in Precrystalline Glucose Aggregates, Department of Chemistry and Department of Chemical Engineering, Michigan State University, East Lansing, Michigan.				
		STRUPAT, K. et al. 2,5-Dihydroxybenzoic Acid: A New Matrix For Laser Desorption-Ionization Mass Spectrometry, International Journal of Mass Spectrometry and Ion Processes, 111 (1991) 89-102				
		VISSER, R.A., et al. A Natural Crystal Growth Retarder in Lactose. Milk Diary J., 1980, pp. 255-75, Vol. 34.				
		WINDHOLZ, M. (editor). Merck Index, 10 th edition, p. 769.				

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